REMARKS:

Applicant has carefully studied the nonfinal Examiner's Action and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Claim Rejections – 35 U.S.C. § 101

Applicant acknowledges the quotation of 35 U.S.C § 101.

Claims 1-7 and 9-14 stand rejected under 35 U.S.C § 101 as being directed to non-statutory subject matter. The instant claims are drawn to a method of screening a mammogram. However, the Office states that, as the method does not recite a physical transformation of matter, the method must be tied to another category of invention to be patentable subject matter (In Re Bilski, No 2007-10030, and decided 10/30/2008).

In an effort to further the prosecution of the case, the claims have been amended to overcome the rejection by the Office and are now believed to be in condition for allowance.

Additionally, Applicant respectfully disagrees with the Office that the method of the instant claims recited in independent claims 1 and 14 does not recite a physical transformation of matter. Both claim 1 and claim 14 recite, "producing an electronic output image of the asymptomatic patient's mammogram that visualizes the detected abnormalities". As such, in accordance with the method of the present invention the mammogram of the asymptomatic patient and the risk factors associated with the patient are used to produce an asymptomatic patient mammogram that visualizes the abnormalities detected by the computer algorithm. Applicant contends that the methods steps of the present invention recite a physical transformation of matter, namely the transformation of a mammogram to a mammogram that visualizes detected abnormalities.

Claim Rejections – 35 U.S.C. § 103

Applicant acknowledges the quotation of 35 U.S.C § 103(a).

Claims 1-5, 9, 10, 12, 13 and 14 stand rejected under 35 U.S.C § 103(a) as being unpatentable over Giger et al. (U.S. 5,133,020) in view of Huo et al. (U.S. 6,282,305).

Regarding claim 1, the Office states that Giger et al. teaches identifying a standard threshold of the computer algorithm for identifying false positive abnormalities that is independent of the array of risk factors (column 6, lines 33-column 9, line 10); and adjusting the threshold for identifying false positives based on the risk associated with an asymptomatic patient (column 12, line 58-column 13, line 7). The Office goes on to state that while Giger et al. does not specifically teach calculating breast cancer risk, that Huo et al. discloses a method which includes establishing a risk probability with a patient with factors such as age (column 5, lines 55-63; column 6, lines 25-40); applying a computer algorithm to find abnormalities in a patient's mammogram (column 9, lines 30-48). The Office concludes that it would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the references of Huo et al. with Giger et al. to gain the benefit of using known risk analysis methods to improve the prognosis or diagnosis of breast cancer based on mammograms. In support of the combination, the Office states that Giger et al. indicates that the threshold may be adjusted for the risk assessment of a patient for better evaluation of a mammogram (column 12, line 58-column 13, line 7) and that based on their recommendation, one of ordinary skill in the art would be motivated to search for a method of calculating breast cancer risk. Huo et al. provides methods of calculating breast cancer risk. One of ordinary skill in the art would be motivated to combine the references of Giger et al. and Huo et al. in order to carry out Giger et al.'s method as he indicates.

Claim 1 has been amended to more clearly describe that which the Applicant regards as the invention.

Amended claim 1 recites, "a method of screening an asymptomatic patient's mammogram to detect abnormalities in the asymptomatic patient's mammogram, wherein

screening the asymptomatic patient's mammogram to detect abnormalities is performed prior to classifying the detected abnormalities as being malignant or benign, the method of screening comprising: establishing a detection risk probability value associated with an asymptomatic patient, the detection risk probability value calculated from an array of risk factors associated with breast cancer; selecting a computer algorithm to detect abnormalities in the asymptomatic patient's mammogram; identifying a standard threshold of the computer algorithm for detecting false positive abnormalities, wherein the standard threshold is independent of the array of risk factors associated with the asymptomatic patient; adjusting the standard threshold of the computer algorithm for detecting false positive abnormalities in response to the risk probability value associated with the asymptomatic patient; detecting abnormalities in the asymptomatic patient's mammogram by applying the computer algorithm using the adjusted standard threshold; and producing an electronic output image of the asymptomatic patient's mammogram that visualizes the detected abnormalities".

As such, it is made clear by the amendment to claim 1 that the detection of abnormalities in the asymptomatic patient's mammogram occurs prior to the classification of the detected abnormalities as being malignant or benign and that the present invention is directed to the detection of abnormalities in an asymptomatic patient's mammogram and not to the classification of the detected abnormalities as being malignant or benign.

Applicant contends that neither Geiger et al. nor Hou et al., alone or in combination, teach the method of the present invention which includes, "screening the asymptomatic patient's mammogram to detect abnormalities is performed prior to classifying the detected abnormalities as being malignant or benign".

Applicant contends that Giger et al. does not teach or suggest a method of screening an asymptomatic patient's mammogram to detect abnormalities which requires adjusting the standard threshold of the computer algorithm for identifying false positive abnormalities in response to a risk probability value associated with the asymptomatic patient as is claimed by the presented, but rather teaches a method of screening a patient's mammogram to identify abnormalities using a standard threshold that is *not* adjusted based on the patient's risk factors.

Giger et al. only suggests adjusting the threshold during the classification process, not during the process of detecting the abnormality.

Additionally, the Office states that Giger et al. does not specifically teach calculating breast cancer risk, but that Huo et al. discloses a method which includes establishing a breast cancer risk probability with a patient with factors such as age. The Office therefore concludes that it would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the references of Huo et al. with Giger et al. to gain the benefit of using known risk analysis methods to improve the prognosis or diagnosis of breast cancer based on mammograms. In support of the combination, the Office states that Giger et al. indicates that the threshold may be adjusted for the risk assessment of a patient for better evaluation of a mammogram (column 12, line 58-column 13, line 7) and that based on their recommendation, one of ordinary skill in the art would be motivated to search for a method of calculating breast cancer risk. Huo et al. provides methods of calculating breast cancer risk. The Office concludes that one of ordinary skill in the art would be motivated to combine the references of Giger et al. and Huo et al. in order to carry out Giger et al.'s method as he indicates.

Applicant respectfully disagrees with this finding by the Office.

As previously stated, the detection process of Giger et al. does not suggest varying the threshold values associated with the detection of abnormalities in an asymptomatic patient's mammogram based on the patient's risk factors. As such, there is no reason to combine the method of establishing a breast cancer risk probability of Huo et al. with the detection method of Giger et al. to arrive at the invention, because Giger et al. does not suggest varying the threshold values for detection purposes based on a patient's risk factors.

For the reasons cited above, Applicant believes that independent claim 1 is not obvious in view of Giger et al. in combination with Huo et al., and is therefore believed to be in condition for allowance.

Claims 2-7 and 9-13 are dependent upon claim 1, and are therefore allowable as a matter of law.

Claim 14 has been amended to more clearly describe that which the Applicant regards as the invention.

Amended claim 14 recites, "a computer implemented method of screening an asymptomatic patient's mammogram to detect abnormalities in the asymptomatic patient's mammogram, wherein screening the asymptomatic patient's mammogram to detect abnormalities is performed prior to classifying the detected abnormalities as being malignant or benign, the method of screening comprising: identifying an average risk for breast cancer based on a set of risk factors; identifying an asymptomatic patient as being either at a high risk for breast or at a low risk for breast cancer based on the set of risk factors for breast cancer for the patient, wherein the patient is at a high risk for breast cancer if their risk is above the average risk and the patient is at a low risk for breast cancer if their risk is below the average risk; identifying a standard false positive detection threshold for the identification of abnormalities in a mammogram; adjusting the standard false positive detection threshold by increasing the standard false positive detection threshold if the asymptomatic patient is at a high risk for breast cancer and decreasing the standard false positive detection threshold if the patient is at a low risk for breast cancer; evaluating the asymptomatic patient's mammogram to detect abnormalities based on the adjusted false positive detection threshold; and producing an electronic output image of the asymptomatic patient's mammogram that visualizes the detected abnormalities.

As such, it is made clear by the amendment to claim 14 that the detection of abnormalities in the asymptomatic patient's mammogram occurs prior to the classification of the detected abnormalities as being malignant or benign and that the present invention is directed to the detection of abnormalities in an asymptomatic patient's mammogram and not to the classification of the detected abnormalities as being malignant or benign.

Applicant contends that neither Geiger et al. nor Hou et al., alone or in combination, teach the method of the present invention which recites, "screening the asymptomatic patient's mammogram to detect abnormalities is performed prior to classifying the detected abnormalities as being malignant or benign".

Applicant contends that Giger et al. does not teach or suggest a method of screening an asymptomatic patient's mammogram to detect abnormalities which requires adjusting the

standard threshold of the computer algorithm for identifying false positive abnormalities in response to a risk probability value associated with the asymptomatic patient, but rather teaches a method of screening a patient's mammogram to detect abnormalities using a standard threshold that is *not* adjusted based on the patient's risk factors. Giger et al. only suggests adjusting the threshold during the classification process, not during the process of detecting the abnormality.

Additionally, the Office states that Giger et al. does not specifically teach calculating breast cancer risk, but the Huo et al. discloses a method which includes establishing a breast cancer risk probability with a patient with factors such as age. The Office therefore concludes that would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the references of Huo et al. with Giger et al. to gain the benefit of using known risk analysis methods to improve the prognosis or diagnosis of breast cancer based on mammograms. In support of the combination, the Office states that Giger et al. indicates that the threshold may be adjusted for the risk assessment of a patient for better evaluation of a mammogram (column 12, line 58-column 13, line 7) and that based on their recommendation, one of ordinary skill in the art would be motivated to search for a method of calculating breast cancer risk. Huo et al. provides methods of calculating breast cancer risk. The Office concludes that one of ordinary skill in the art would be motivated to combine the references of Giger et al. and Huo et al. in order to carry out Giger et al.'s method as he indicates.

Applicant respectfully disagrees with this finding by the Office.

As previously stated, the detection process of Giger et al. does not suggest varying the threshold values associated with the detection of abnormalities in an asymptomatic patient's mammogram based on the patient's risk factors. As such, there is no reason to combine the method of establishing a breast cancer risk probability of Huo et al. with the detection method of Giger et al. to arrive at the invention, because Giger et al. does not suggest varying the threshold values for detection purposes based on a patient's risk factors.

For the reasons cited above, Applicant believes that amended independent claim 14 is not obvious in view of Giger et al. in combination with Huo et al., and is therefore believed to be in condition for allowance.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned is requested.

Very respectfully,

SMITH & HOPEN

/molly l sauter/

By:_____

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Dated: February 4, 2009
Reg. No.: 46,457

CERTIFICATE OF ELECTRONIC TRANSMISSION

(37 C.F.R. 1.8(a))

I HEREBY CERTIFY that this correspondence is being electronically transmitted to the Patent and Trademark Office through EFS Web on February 4, 2009.

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Erica Gossage